

**510(k) Summary  
Stöckert S5 System**

K060053

**1. SPONSOR**

Sorin Group Deutschland GmbH  
Lindberghstrasse 25  
80939 Munich  
Germany  
Contact Person: Helmut Höfl  
Telephone: 011 49 89 323 010

Date Prepared: January 4, 2006

**2. DEVICE NAME**

Proprietary Name: Stöckert S5 System  
Common/Usual Name: Heart lung machine  
Classification Name: Multiple

**3. PREDICATE DEVICES**

Stöckert S3 System (multiple 510(k) numbers)

**4. DEVICE DESCRIPTION**

The Stöckert S5 System, like the parent S3 System, is a modular system consisting of a console, various pumps, monitors, displays, controls, and user interfaces.

**5. INTENDED USE**

The Stöckert S5 System is intended to be used during cardiopulmonary bypass surgery lasting six (6) hours or less.

**6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

The Stöckert S5 System is an upgrade of the Stöckert S3 System. The Stöckert S5 System is substantially equivalent to the Stöckert S3 System based on intended use, indication for use, operational characteristics, and fundamental technological characteristics.

**7. PERFORMANCE TESTING**

Testing of the Stöckert S5 System demonstrated that the System fulfills prospectively defined performance criteria and included electrical safety, electromagnetic compatibility, software validation, and functional testing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN -2 2006

Medical Device Consultants, Inc.  
c/o Ms. Rosina Robinson  
Senior Staff Consultant  
49 Plain Street  
North Attleboro, MA 02760

Re: K060053  
Stöckert S5 System  
Regulation Number: 21 CFR 870.4220  
Regulation Name: Heart Lung Machine Console  
Regulatory Class: Class II  
Product Code: DTQ  
Dated: May 22, 2006  
Received: May 23, 2006

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Rosina Robinson

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Stöckert S5 System

Indications for Use:

The Stöckert S5 System is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

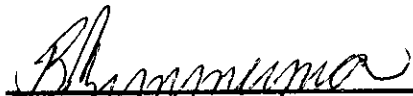
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use       
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K060053

page 1 of 1